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10/534,259	02/28/2006	William James	P-7938-US	4967
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PEARL COHEN ZEDEK LATZER, LLP			EXAMINER	
1500 BROADWAY 12TH FLOOR			KINSEY, NICOLE	
NEW YORK, NY 10036			ART UNIT	PAPER NUMBER
			1648	
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			07/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/534,259

Applicant(s)

JAMES ET AL.

Examiner

Nicole E. Kinsey, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7 and 13-17 is/are rejected.
- 7) ☐ Claim(s) 5,10,11 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/28/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' election with traverse of claims 1-7, 10-18 in the reply filed on May 10, 2007 is acknowledged. The elected claims correspond to Groups I and II. On May 22, 2007, the Examiner contacted Guy Levi via telephone to discuss the election. Mr. Levi indicated the initial election of two groups was an error and proceeded to elect group I (claims 1-7, 10-11 and 13-18). The traversal is on the grounds that i) the oligonucleotides disclosed by Wyatt et al. bind to the V3 loop, which is not the case for the instantly claimed oligonucleotides and ii) the sequences of claim 5 share a common function (i.e., binding to a conserved core sequence on gp120) and therefore should be examined together. This is not found persuasive.

The claims are drawn to nucleic acids that bind to an envelop glycoprotein of an enveloped virus, wherein binding of said nucleic acid results in neutralization. Wyatt discloses nucleic acids that bind to an envelop glycoprotein (gp120) of an enveloped virus (HIV), wherein binding of said nucleic acid resulted in neutralization. Therefore, the technical feature does not make a contribution over the prior art.

Although the sequences of claim 5 share the function of binding to virus, the sequences do not share a common core sequence. Therefore, a search for one sequence will not be commensurate in scope with a search for any other sequence. Furthermore, search burden is not considered when analyzing unity of invention for applications filed under 35 U.S.C. §371.

The requirement is still deemed proper and is therefore made FINAL.

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The claim status identifiers used in the preliminary amendment filed May 10, 2005 are not in accordance with 37 CFR 1.121. For purposes of compact prosecution, the examiner has proceeded with examination of this application, however, any subsequent claim listing must use the correct status identifiers in order for entry of the amendment.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Appropriate correction is required.

### ***Claim Objections***

Claims 15-17 are objected to because of the following informalities:

Claim 15 does not end with a period.

Claim 15 should recite "wherein said purine" or "wherein the purine."

Claims 16-17 should recite "wherein said pyrimidine" or "wherein the pyrimidine."

Claim 17 has no status identifier (e.g., New). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites that the pyrimidine base is modified at the 6 or 8 position. According to the structure of a pyrimidine in Alberts et al. (Molecular Biology of the Cell, 2<sup>nd</sup> Edition, page 56), there is no position 8. Further, claims 13 and 15 state that the purine base is modified at the 5 position. Again, according to the structure of a pyrimidine in Alberts et al., this is an unlikely position on a purine to have a modification. The metes and bounds of the claims cannot be determined without further clarification regarding the positions of the modifications.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Buckheit et al. (AIDS Research and Human Retroviruses, 1994, 10(11):1497-1506).

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The claims are drawn to a nucleic acid molecule capable of binding to an envelope glycoprotein of an enveloped virus, wherein the binding of said nucleic acid molecule results in neutralizing said virus.

Buckheit et al. discloses nucleic acids that bind to an envelope glycoprotein (gp120) of an enveloped virus (HIV-1 and HIV-2), wherein binding of said nucleic acid inhibits both cell-to-cell and virus-to-cell infection (i.e., binding results in neutralization).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Wyatt et al. (Proc. Natl. Acad. Sci. USA, 1994, 91, 1356-1360).

Wyatt discloses nucleic acids that bind to an envelope glycoprotein (gp120) of an enveloped virus (HIV-1), wherein binding of said nucleic acid inhibits both cell-to-cell and virus-to-cell infection (i.e., binding results in neutralization).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ecker et al. (Nucleosides & Nucleotides, 1995, 14(3-5):1117-1127).

Ecker et al. discloses nucleic acids that bind to an envelope glycoprotein (gp120) of an enveloped virus (HIV-1 and HIV-2), wherein binding of said nucleic acid inhibits both cell-to-cell and virus-to-cell infection (i.e., binding results in neutralization).

Claims 1-4, 6, 7 and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Macejak et al. ( U.S. Patent Application No. 2004/0006035), evidenced by Usman et al. (TIBS, 1992, 17:334-339).

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Macejak et al. discloses nucleic acid aptamers that bind to an envelope glycoprotein (gp120 and/or gp41) of an enveloped virus (HIV-1), wherein binding of said nucleic acid inhibits HIV viral fusion, cell entry, gene expression and replication (i.e., binding results in neutralization) (see, for example, Abstract and Summary of the Invention). Macejak et al. also teaches that the bases of the nucleotides of the aptamers may be modified by methods known in the art to enhance stability and/or enhance biological activity (see, for example, paragraphs [0035], [0149], [0166] and [0171]). Some modifications include modifications at the 2, 5 and 6 positions of purine and pyrimidine bases with methyl, amino groups, and halide groups and modifications found in Usman et al. (TIBS, 1992, 17:334-339), which is enclosed for applicants to review.

SEQ ID NO:1 is free of the prior art. Claims 5, 10, 11 and 18, as they read on SEQ ID NO:1, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is



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(571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole E. Kinsey, Ph.D.  
Examiner  
Art Unit 1648

/nk/

/Stacy B. Chen/ 7-18-2007  
Primary Examiner, TC1600